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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,643	10/20/2000	Pramod K. Srivastava	8449-073-999	8419

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/11/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,643

Applicant(s)

SRIVASTAVA, PRAMOD K.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,9,13,17,21,25-42,44,46 and 82-99 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 4,9,13,17,21,25-42,44,46 and 82-99 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11. 6) ☐ Other: _____

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DETAILED ACTION

1. The amendment filed 1/8/2003 (paper no. 10) is acknowledged and entered into the record.
2. Claims 48-65 are newly added. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).
3. Misnumbered claims 48-65 have been renumbered 82-99.
4. Claims 4,9,13,17,21,25-42,44,46-47, 82-99 are pending and examined on the record.

Claim Rejections Withdrawn - 35 USC § 112, 2nd paragraph

5. The rejection of claim 44 under 35 USC 112, 2nd paragraph as being indefinite is withdrawn in view of the amendments to the claims and the persuasive arguments set forth by the applicant.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

The rejection of claims 4,9,13,17,21,25-42,44,46-47, and now 82-99 under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the use of vaccines in conjunction with HSPs are enabled by the instant specification. Applicant further argues that the specification presents ample teaching and further states that the art of record provides guidance to one of skill in the art as to how to use the instant method for the prevention of cancer. Applicant's

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arguments have been carefully considered but are not found persuasive for the following reasons. The administration of HSPs and a vaccine composition for the prevention of cancer is intended to elicit an immune response to the vaccine composition, wherein the HSP is only intended to act as an adjuvant so as to increase the efficacy of the vaccine composition. Nowhere in the specification has it taught to one of skill in the art how to use the instant vaccine composition as a prophylactic composition so as to prevent the formation of cancer. There is no disclosure within the specification or in the art that would guide the skilled artisan to administer a vaccine to any and all individuals so as to prevent the formation of any and all types of cancer. The specification is devoid of studies needed to establish a vaccine so as to prevent the formation of cancer. Such methods would include challenge studies wherein a patient is administered the vaccine-HSP compound and then subsequently challenged with cancerous cells. The specification is devoid of such teachings, therefore, the artisan cannot be properly guided in a method of prevention using the invention of the instant application. The specification has only taught a method of treating a pre-existing cancer with a medicament and HSP60, HSP70, and gp96, and not the broad genus of any and all HSPs for the prevention of cancer with a vaccine. The administration of a vaccine to a subject within a population that is not in need of such treatment would cause a permanently heightened immune response. Although the administration of the vaccine in combination with the HSP may eliminate cancer, the overactivated immune state may eventually lead to other diseases such as autoimmune disease. The specification has not disclosed whether such diseases are or will likely develop as a result of the instant invention. Furthermore, there is no art of record that teaches which members of the population are to

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receive cancer treatments or prevention medicaments because it is not known which members of the population will develop cancer. Although the specification has taught how to make and use a medicament for the treatment of cancer, wherein the medicament comprises an tumor or cancer related antigen in conjunction with HSP70, HSP90, and gp96, it has not taught how to prevent cancer, and which members within a given population would be in need of the instant invention, using a cancer vaccine in conjunction with any and all HSPs.

Claim Rejections Withdrawn - 35 USC § 103

6. The rejection of claims 26-31 under 35 USC 103(a) as being obvious over Chen *et al* is withdrawn in view of the persuasive arguments set forth by the applicant. Claims 4,9,33,42,44, and 46 are maintained.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 4,9,13,27,30,33,42,44, 46, and now newly added claims 82, 86, 90, 93, 94, 95, and 97 under 35 USC 102 (a) as being anticipated by Chen *et al* is maintained for the reasons of record. Applicant argues that the prior art does not teach each and every element of the instant invention because the vaccine used by Chen *et al* is the same substance as the HSP, whereas the instant invention claims a vaccine which is immunogenically different from the HSP molecule. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons. The claims of the instant invention are drawn to a method of treating or preventing cancer comprising the administration of a vaccine composition comprising a component that displays antigenicity of a cancer cell and a HSP which does not display immunogenicity of the vaccine component. The fusion protein disclosed by Chen *et al* has two separate

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and distinct portions, namely the E7 antigenic portion and the HSP70 portion. Both of which have different and distinct immunogenic determinants. Therefore, regardless of the fusion of the two portions, the immunogenicity of the two proteins which in this case are fused together, are different. Chen *et al* anticipates newly added claims because the HSP and the tumor antigen are administered simultaneously, and the HSP protein as disclosed by Chen *et al* enhances the ability of the E to elicit an immune response.

Claim Rejections Maintained - 35 USC § 103

8. The rejection of claims 4,9,33,42,44, 46 and now newly added claims 82,86,90, 94,95 and 97 under 35 USC 103(a) as being obvious over Chen *et al* is maintained for the reasons of record. Applicant argues that the Chen *et al* reference teach the administration of a fusion protein vector and hence does not teach or suggest that it can be administered in different phases of administration. Examiner concedes that the administration of the composition before or after is not motivated or suggested by Chen *et al* however, the Chen *et al* does not specifically teach the concurrent nor the administration of the composition on the same day. However, it would have been *prima facie* obvious to administer the composition on the same day and concurrently, because the vector used as the medicament for the treatment of cancer was contained within the same plasmid/vector and hence one of ordinary skill in the art would have found it obvious to administer a composition on the same day and concurrently.

Claim Rejections Maintained - 35 USC § 103

9. The rejection of claims 4,9,13,17,21,25-42,46, and now newly added claims 82, 83, 86, 90, 93, 94, 95, and 97 under 35 USC 103(a) as being obvious over Yang *et al* in view of either Suzue *et al* or Chen *et al* is maintained for the reasons of record.

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Applicant argues that the teachings of Yang *et al* in combination with either Suzue *et al* or Chen *et al* do not obviate the instant invention because Yang *et al* do not teach the use of tumor associated antigens with HSPs and that both Suzue *et al* and Chen *et al* teach HSP fusion proteins which are not immunogeneically different from the antigen. See paragraph 8 above for the Chen *et al* arguments. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons. The use of tumor associated antigens was well known and established in the art as a means to generate an immune response to an antigen found on tumor cells. The use of HSP as an immune regulator or stimulator was also well known and practiced in the art at the time of filing. It is therefore obvious to combine the teachings of two methods to develop a method of treating cancer because it was already known in the art to practice either invention separately. The instant invention has not exemplified to one of ordinary skill in the art that the instant invention has any unexpected results or synergistic effects when combined together to treat cancer. Therefore, the method of combining is considered obvious over the art.

New Claim Rejections - 35 USC § 112, 2nd paragraph

10. Claims 93-99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Regarding claims 93-99 in the recitation of the term "effective amount", it is unclear as to what amount are intended to accomplish the desired task. The specification has not provided any disclosure so as to lead one of skill in the art to determine what amounts are effective in treating or preventing cancer.

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12. Regarding claims 93-99 in the recitation of the term “increase”, it is considered a relative term because there is no comparison to a base level. As such one of skill in the art would not know how much of an “increase” is considered an elevation over normal.

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-4242

for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
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March 9, 2003

ALR
ALR. SALIMI
PRIMARY EXAMINER